STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner **File No. 92964-001**

v

Blue Cross Blue Shield of Michigan
Respondent
_____/

Issued and entered
this 12th day of November 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On August 29, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq*. The Commissioner reviewed the material submitted and accepted the request on September 8, 2008.

Because it involved medical issues the Commissioner assigned the case to an independent review organization which provided its analysis and recommendations to the Commissioner on September 17, 2008.

II
FACTUAL BACKGROUND

The Petitioner receives health care benefits from Blue Cross Blue Shield of Michigan (BCBSM) through the Michigan Education Special Services Association (MESSA), an underwritten group. Coverage is governed by MESSA's *Choices II Group Insurance for School Employees* certificate of coverage (the certificate).

The Petitioner has suffered from back pain for many years as well as headaches and knee pain. Her doctor prescribed an RS-4i sequential stimulator (also known as a RS-4i channel monitor) to treat her conditions. From August 29, 2007, through October 29, 2007, the Petitioner rented a RS-4i device, an item of durable medical equipment. The rental charge was $385.00.

BCBSM denied coverage for the RS-4i device because it believes it to be experimental or investigational for the Petitioner's condition. The Petitioner appealed BCBSM's denial. BCBSM did not respond to the Petitioner's grievance appeal within the required 35 days, so she is eligible for an external review.

III
ISSUE

Did BCBSM properly deny payment for the Petitioner's RS-4i device?

IV
ANALYSIS

Petitioner's Argument

The Petitioner's doctor prescribed an RS-4i and a back brace for her. The Petitioner says she called MESSA-BCBSM to make sure the items were covered and was told they were. Since the company that furnishes this device has a BCBSM provider number, the Petitioner was confident that this equipment would be paid by her insurance.

After a few months the Petitioner received a statement that her RS-4i device was not a covered benefit. She called MESSA-BCBSM and was told a TENS unit was covered to treat pain but the RS-4i was not covered. The Petitioner argues that the TENS unit only treats pain while the RS-4i treats both pain and muscle.

The Petitioner indicates she has suffered from back and knee pain for many years and has tried everything to relieve it. She believes that her RS-4i device has helped her and is medically necessary. She does not believe it is experimental or investigational treatment and it should be paid for by MESSA-BCBSM.

BCBSM's Argument

BCBSM says the RS-4i device provided the Petitioner is experimental or investigational and therefore not a covered benefit. It points to this provision in "Section 10: Exclusions and Limitations" of the certificate (pages 48-49):

> The following exclusions and limitations apply to the MESSA Choices II program. These are in addition to limitations appearing elsewhere in the coverage booklet.
>
> * * *
>
> - services and supplies that are not medically necessary according to accepted standards of medical practice including any services which are experimental or investigational

The certificate (page 4) defines the term "experimental or investigational" as "[a] service that has not been scientifically demonstrated to be as safe and effective for treatment of the patient's condition as conventional or standard treatment."

In the Petitioner's case, BCBSM asserts that the efficacy of the RS-4i device has not been proven to be as safe and effective for the treatment of the patent's condition as conventional treatment. BCBSM believes it has not proved to be as effective in relieving acute or chronic pain as a conventional TENS unit. After review, BCBSM confirmed that the device is considered to be experimental or investigational.

Commissioner's Review

The certificate sets forth the benefits that are covered. A procedure that is not accepted as the standard of care and has not been demonstrated to be as safe or effective as conventional or standard treatment is considered to be experimental or investigational and is not a benefit under the terms of the Petitioner's coverage.

The question of whether the Petitioner's RS-4i device is experimental or investigational for treatment of her condition was presented to an independent review organization (IRO) for analysis as required by section 11(6) of PRIRA. The IRO physician reviewer is board certified in orthopedic surgery and has been in active practice for more than fifteen years.

The IRO physician reviewer concluded that the RS-4i is investigational for treatment of the Petitioner's condition. The IRO report said:

> The MAXIMUS physician consultant explained that there is no class I data from randomized controlled trials to support the use of the RS-4i sequential stimulator for the treatment of low back pain. The MAXIMUS physician consultant also explained that more long term outcomes data is needed regarding the efficacy of this device for the treatment of low back pain. The MAXIMUS physician consultant indicated that RS-4i sequential stimulator is investigational for treatment of chronic low back pain at this time.
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> Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the RS-4i sequential stimulator that the [Petitioner] received is investigational for treatment of her condition.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why that judgment should be rejected in the present case.

Therefore, the Commissioner accepts the conclusion of the IRO and finds that the Petitioner's RS-4i device is investigational for treatment of her condition and is therefore not covered under the terms of the Petitioner's certificate.

V
ORDER

Respondent BCBSM's decision to deny coverage for the Petitioner's RS-4i device is upheld because it is investigational for treatment of her condition.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review

should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.